

REMARKS

This paper is filed in response to the Office Action dated June 12, 2009. Claims 1, 4, 7, 8, 26-31, and 47 are pending in the Application, claims 7 and 8 are withdrawn from consideration, and claims 1, 4, 26-31 and 47 stand rejected. By this paper, claim 1 is amended and claims 4, 7, 8, 26-31, and 47 remain as previously presented. It is respectfully submitted that the amendments to claim 1 add no new matter to the Application; support for the amendments can be found, for example, in paragraphs [0045], [0046], [0051], [0137], and [0138] and in Figs. 8A-8F of the Application as filed. Reconsideration of the Application in view of the amendments and the following remarks is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 28-31, and 47 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,485,513 that issued to Fan ("Fan") in view of U.S. Patent No. 6,063,114 that issued to Nash et al. ("Nash"); claims 4 and 26 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fan and Nash in view of U.S. Patent No. 6,482,227, which issued to Solovay ("Solovay"); and claim 27 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fan and Nash in view of U.S. Patent No. 6,428,550, which issued to Vargas et al. ("Vargas"). The Applicants respectfully traverse these rejections. However, in order to expedite prosecution of the Application, independent claim 1 has been amended.

Claim 1

The Applicants respectfully submit that amended claim 1 is not obvious in view of Fan and Nash, whether these references are considered individually or in combination. For example, amended claim 1 recites, *inter alia*, that a “vein, at a position of the vein opening, has an inner diameter equal to or smaller than the outer diameter defined by the stent when in an uncompressed state.” No such feature is disclosed in Fan or Nash. For example, as shown in FIG. 4 of Fan (reproduced below, with edits), the diameters **D1**, **D2** defined by the anchor hooks 9 that are associated with the grafts 10, 10' are each significantly smaller than an inner diameter **D3** of a natural vessel 20. This is due to the “true end-to-side” arrangement that is required by Fan, which is described in part as follows:

[T]he anchor hooks 9 and membrane 9a reside inside of the vessel 20 and bear against the inner wall 20a of the vessel, thus preventing dislodgement of the graft 10 from the vessel. FIG. 4 further shows a second graft 10' in a perspective view from outside the vessel. As shown, the grafts 10, 10' join the vessel at substantially normal incidence. Further, as seen in the partial cut away view, within the vessel the graft ending lies closely against and fastens tangent to the endoluminal surface of the vessel wall without projecting into the blood flow lumen 21.

Fan, col. 3, lines 32-37. It is unclear how such an arrangement would be possible if the inner diameter **D3** of the natural vessel 20 were instead equal to or smaller than the diameters **D1**, **D2** defined by the anchor hooks 9. Nash fails to remedy any of these shortcomings of Fan.

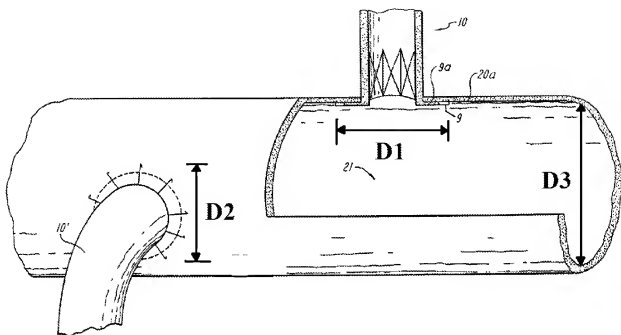


FIG. 4 of Fan (Edited)

Moreover, amended claim 1 recites, *inter alia*, yielding “an **end-to-end** anastomosis in which a portion of the vein to which the second end of the graft vessel is anastomosed becomes a terminal portion of the vein” (emphasis added). No such feature is disclosed in Fan or Nash. Indeed, Fan emphasizes the desirability of forming a “true” or “pure” **end-to-side** anastomosis, in contrast to prior art devices that “partially obstruct a vessel or divert flow . . .” Fan, col. 1, lines 45-54 and 62-63; col. 2, lines 14-18; col. 3, lines 24-37.

Accordingly, it is respectfully submitted that modifying the disclosure of Fan to achieve an end-to-end anastomosis such as that recited in claim 1 would impermissibly render Fan unsatisfactory for its intended purpose (i.e., the creation of a “true” end-to-side anastomosis”). See M.P.E.P. § 2143.01 (V). Such a modification also would

impermissibly change the principle of operation of this reference. See *id.* at § 2143.01 (VI). Moreover, such modifications would not be obvious in view of Nash, since this reference likewise discloses only an end-to-side anastomosis arrangement. See, e.g., Nash, FIGS. 2, 7, 8, 10, 12, 13, and 14; col. 6, lines 42-59; col. 9, lines 18-26; col. 10, lines 47-67; and col. 11, lines 1-6.

The instant Application clearly distinguishes between end-to-end anastomoses and end-to-side anastomoses. For example, as described in paragraph [0045] of the specification, “[a]n anastomosis is termed end-to-end when the terminal portions of tubular structures are anastomosed, and it is termed end-to-side when the terminal portion of a tubular structure is anastomosed to a lateral portion of another tubular or hollow structure.” In paragraph [0046], the specification indicates that the stented end of a graft vessel is attached to a vein in an end-to-end anastomosis, and an example of such a procedure is described in paragraphs [0134]-[0138] and depicted in FIGS. 8A-8F.

In view of at least the foregoing, the Applicants respectfully submit that Application clearly supports the recitation in amended claim 1 of “removing the sheath from the vein such that the second end of the graft vessel is anastomosed to the vein to yield an end-to-end anastomosis in which a portion of the vein to which the second end of the graft vessel is anastomosed becomes a terminal portion of the vein.” Furthermore, the Applicants respectfully submit that such an arrangement would not be obvious in view of either Fan or Nash. For at least the foregoing reasons, the

Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 103(a) be removed.

Claims 4, 26-31, and 47

Each of claims 4 and 26-31 depends from independent claim 1 and thus includes all of the limitations of this claim. Therefore, for at least the reasons discussed above with respect to claim 1, the Applicants respectfully submit that none of the references Fan, Nash, Solovay, and Vargas, whether considered individually or in combination, render obvious any of claims 4, 26-31, and 47. The Applicants thus respectfully request that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

Rejoinder

The Applicants respectfully submit that amended independent claim 1 is generic to at least withdrawn claims 7 and 8. Further, as discussed above, the Applicants respectfully submit that claim 1 is allowable. Therefore, the Applicants hereby request rejoinder of claims 7 and 8 because each of these claims depends from an allowable independent claim and requires all the limitations of the independent claim from which it depends. See M.P.E.P. § 821.04.

Conclusion

In view of the foregoing, it is believed that all of the pending claims are patentable in their present form and thus a Notice of Allowance for this case is respectfully requested. The Applicants respectfully note that it is the combination of

features recited in a claim that renders the claim patentable, and not any feature or features of the claim in isolation. Accordingly, the Applicants respectfully submit that none of the references discussed above, whether considered individually or in combination, renders obvious:

[a] method for connecting a vessel to another vessel comprising:

providing a synthetic graft vessel having a first end and a second end, the second end coupled with a stent such that portions of the stent are fixedly attached to the second end of the graft vessel, wherein the stent defines an outer diameter when in an uncompressed state;

anastomosing the first end of the graft vessel to a side of an artery to yield an end-to-side anastomosis;

inserting an introducer into a vein at a vein opening;

inserting a sheath into the vein such that, when both the introducer and the sheath are in the vein, at least a portion of the introducer is within the sheath;

removing the introducer from the vein;

inserting, after removal of the introducer from the vein, the second end of the graft vessel into the sheath such that at least a portion of the stent is within the vein, wherein the vein, at a position of the vein opening, has an inner diameter equal to or smaller than the outer diameter defined by the stent when in an uncompressed state; and

removing the sheath from the vein such that the second end of the graft vessel is anastomosed to the vein to yield an end-to-end anastomosis in which a portion of the vein to which the second end of the graft vessel is anastomosed becomes a terminal portion of the vein,

as recited in independent claim 1. Likewise, none of the methods recited in dependent claims 4, 7, 8, 26-31, and 47 are obvious in view of the cited references.

The Examiner is invited to contact the undersigned attorney should any impediment to the prompt allowance of this Application remain that is susceptible to being clarified by a telephonic interview or overcome by an examiner's amendment.

DATED this 10th day of December, 2009

Respectfully submitted,

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